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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BAUM, STUART F

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 12/15/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/072,077

Applicant(s)

GALLIE ET AL.

Examiner

Stuart F. Baum

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-14,17-22 and 25-27 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-14,17-22 and 25-27 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: _____.

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DETAILED ACTION

1. The amendment filed 9/24/2004 has been entered.
2. Claims 1, 4-14, 17-22, and 25-27 are pending and said claims including SEQ ID NO:1 are examined in the present office action.
3. Rejections and objections not set forth below are withdrawn.
4. The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

Written Description

5. Claims 1, 4-14, 17-22, and 25-27 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the office action mailed 6/17/2004. Applicant's arguments filed 9/24/2004 have been fully considered but they are not persuasive.

Applicants contend that there is no ban on functional language to define nucleic acids (page 8, 4th paragraph). Applicants contend that the SAG12 promoter is known in the art and that regions of the SAG12 promoter have been identified that are responsible for the senescence-specific regulation (paragraph bridging pages 8 and 9).

The office contends that designating a promoter by function, i.e., a programmed cell death inducible promoter, or a promoter from a floret specific gene, does not satisfy the written description requirements. Applicants have not disclosed a representative number of

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polynucleotide sequences that are programmed cell death inducible promoters, or promoters that are from floret specific genes. In addition, Applicants have disclosed information for only the Arabidopsis SAG12 promoter, and not for any SAG12 promoter. Given the lack of a representative number of SAG12 promoters from a representative number of plants, Applicants have not fulfilled the written description requirement for any SAG12 promoter.

Applicants contend that an exemplary enzyme involved in cytokinin synthesis is IPT. Applicants contend that the written description requirement has been met (page 9, 2nd and 3rd paragraphs).

Applicants' claims are drawn to any enzyme that catalyzes the synthesis of cytokinins, not just the IPT enzyme. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Scope of Enablement

6. Claims 1, 4-14, 17-22, and 25-27 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a construct comprising the nucleic acid sequence encoding the isopentenyl transferase (IPT) protein used by Applicant operably linked to the Arabidopsis senescence-associated SAG12 promoter introduced into embryogenic maize callus, plants regenerated from the embryogenic callus and transgenic plants exhibiting two embryos and fused endosperm in the maize seeds, does not reasonably provide enablement for claims drawn to a transgenic maize plant or method of inhibiting programmed cell death in a maize plant or a transgenic maize plant comprising introducing a construct comprising a

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programmed cell death inducible promoter operably linked to a nucleotide sequence that inhibits programmed cell death, or wherein the programmed cell death inducible promoter is any SAG12 promoter, or wherein the promoter is from a floret specific gene. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. This rejection is maintained for the reasons of record set forth in the Official action mailed 6/17/2004. Applicant's arguments filed 9/24/2004 have been fully considered but they are not persuasive.

Applicants contend that the specification discloses how to identify promoters useful in the invention and discloses how the SAG12 promoter can be used to identify related promoters in Arabidopsis or other plants (page 10, 3rd and 4th paragraphs). The Applicants contend that the specification discloses plant growth regulators that are known to inhibit programmed cell death and that genes controlling cytokinin synthesis are known in the art, (see Li et al).

The Office contends that undue trial and error experimentation would be required by one of skill in the art to identify other SAG promoters or even other SAG12 promoters from plants other than Arabidopsis. Further, it is unclear how the SAG12 promoter can be used to identify programmed cell death inducible promoters not related to the SAG12 promoter as commensurate in scope with the claims. In addition, the Li et al only teach an IPT gene and do not disclose other cytokinin synthesizing enzymes that can be used in Applicants' invention. Applicants' claims are broadly drawn to any enzyme that catalyzes the synthesis of cytokinin but Applicants and the prior art only teach the IPT gene from Agrobacterium. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

35 USC § 103

7. Claims 1, 4-14, 17-22, and 25-27 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Amasino et al (November, 1997, U.S. Patent Number 5,689,042, listed in IDS). This rejection is maintained for the reasons of record set forth in the Official action mailed 6/17/2004. Applicant's arguments filed 9/24/2004 have been fully considered but they are not persuasive.

Applicants contend that the office action provides no reasoning or evidence to show why one of skill would be motivated to alter the Amasino et al teachings or why such a person would have a reasonable expectation of success (page 12, 1st full paragraph).

The Office contends that it is known in the art that senescence is a general biochemical process that occurs in plants to various organs, e.g., leaves and flowers. The state-of-the-art does not differentiate between leaf senescence and flower senescence. Given that a floret of a maize plant is simply another name for a grass flower, and given absent evidence to the contrary, that leaf senescence is not different from flower senescence, it would have been obvious to one of skill in the art, to use the exact construct of Amasino et al, and to transform maize therewith, to inhibit the senescence of the lower floret.

Applicants contend the the same claims have been rejected for lack of enablement at the same time being rejected for allegedly being obvious over the prior art. Applicants contend that it is simply not possible for Amasino et al to teach one of skill how to practice the invention, while the combination of teachings of the same reference and the present application does not (page 12, 2nd full paragraph).

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The Office contends that the prior office action dated 6/17/2004, acknowledged Applicants' enablement of claims drawn to the Arabidopsis SAG12 promoter operably linked to a nucleic acid encoding the IPT enzyme and maize plant transformation therewith. Applicants are not enabled for claims drawn to any enzyme involved in cytokinin synthesis operably linked to any programmed cell death inducible promoter, or any promoter that directs expression in the lower floret and plant transformation therewith. In addition, the obvious rejection is directed to claims drawn to the Arabidopsis SAG12 promoter operably linked to a nucleic acid encoding the IPT enzyme. Thus, the scope of what Applicants are enabled for is also obvious in view of the prior art. Therefore, there is not an overlap between the non-enabled subject matter and the subject matter encompassed by the obvious rejection.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claim 19 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 19 is drawn to a seed of the transformed plant. Due to Mendelian inheritance of genes, a single gene introduced into a parent plant would only be transferred at most to half the male gametes and half the female gametes. This translates into only three quarters of the progeny having at least a single copy of the transgene and one quarter of the progeny would not carry a copy of the transgene. Given that there is no indication that there would be any other distinguishable characteristics of the claimed progeny (seeds), it is unclear whether the claimed

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seeds would be distinguishable from seeds that would occur in nature. See *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948), and *In re Bergy, Coats, and Malik* 195 USPQ 344, (CCPA) 1977. The amendment of the claims to recite that the seeds comprise the construct that was introduced into the parent seed would overcome the rejection.

9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 571-272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Stuart F. Baum Ph.D.
Patent Examiner
Art Unit 1638
December 8, 2004

Phuong T. Bui
12/10/04
PHUONG T. BUI
PRIMARY EXAMINER